Original Research

Prior Ultrasound-Indicated Cerclage

Comparison of Cervical Length Screening or History-Indicated Cerclage in the Next Pregnancy

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OBJECTIVE: To evaluate outcomes of women with prior ultrasound-indicated cerclage, who in their subsequent pregnancy were either followed by transvaginal ultrasound cervical length screening or received a planned history-indicated cerclage.

METHODS: Multicenter cohort study of singleton gestations with a prior ultrasound-indicated cerclage performed from 1994 to 2014. We evaluated three pregnancies in the study participants: first pregnancy with prior spontaneous preterm birth at less than 37 weeks of gestation; second pregnancy with ultrasound-indicated cerclage for cervical length 25 mm or less; and the third index pregnancy managed with either transvaginal ultrasound cervical length screening with ultrasound-indicated cerclage for cervical length 25 mm or less or planned history-indicated cerclage. The primary outcome was incidence of spontaneous preterm birth at less than 37 weeks of gestation. We planned a subgroup analysis for women who delivered at less than 32 weeks of gestation compared with 32 weeks of gestation or greater in their prior ultrasound-indicated cerclage pregnancy.

RESULTS: Of 102 singleton gestations included, 38 (37.3%) were followed with transvaginal ultrasound cervical length screening and 64 (62.7%) underwent history-indicated cerclage. Of 38 women in the transvaginal ultrasound group, 18 (47.4%) underwent ultrasound-indicated cerclage for cervical length 25 mm or less. After adjusting for confounders, the rate of spontaneous preterm birth at less than 37 weeks of gestation was similar between transvaginal ultrasound cervical length screening and history-indicated cerclage groups (36.8% compared with 43.8%; adjusted odds ratio 0.77, 95% confidence interval 0.47–1.45). Secondary outcomes were also similar in both groups. All women (n=7) who delivered at less than 32 weeks of gestation in their prior pregnancy and subsequently had transvaginal ultrasound screening received ultrasound-indicated cerclage in the index pregnancy compared with only 35.5% of women who delivered at 32 weeks of gestation or greater in their prior pregnancy.

CONCLUSION: Women with prior ultrasound-indicated cerclage have similar outcomes if they receive either transvaginal ultrasound cervical length screening with ultrasound-indicated cerclage for cervical length 25 mm or less or planned history-indicated cerclage in the subsequent pregnancy. Less than 50% of the transvaginal ultrasound cervical length screening group require a repeat ultrasound-indicated cerclage in the subsequent pregnancy.

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LEVEL OF EVIDENCE: II

Preterm birth is a leading cause of perinatal morbidity and mortality.[1] Cervical cerclage is an obstetric procedure performed to prevent spontaneous preterm birth.[2] Currently cerclage is placed in singleton gestations for three indications[3–6]: history-indicated–multiple prior early spontaneous preterm

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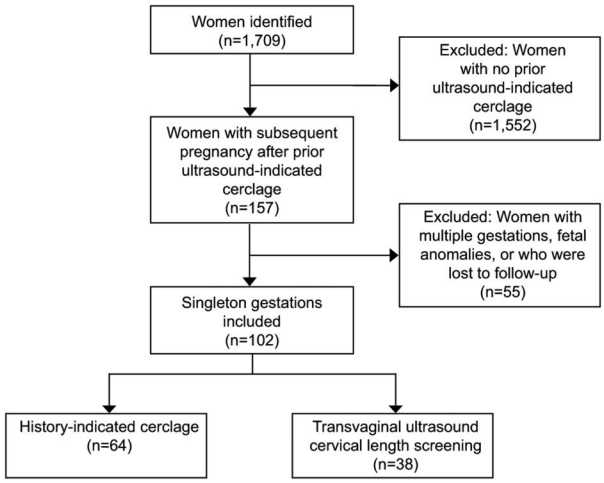

Fig. 1. Study algorithm.

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births or second-trimester losses[7]; ultrasound-indicated–cervical length 25 mm or less in women with prior spontaneous preterm birth[4]; and physical examination-indicated–cervical dilation on physical examination before 24 weeks of gestation.[8–10]

Women with prior spontaneous preterm birth are usually managed in the subsequent pregnancy with serial cervical length screening approximately every 2 weeks between 16 and 24 weeks of gestation.[11–13] Approximately 42% of these women develop short cervix (25 mm or less) before 24 weeks of gestation, and an ultrasound-indicated cerclage is placed for prematurity prevention.[4] These women with prior ultrasound-indicated cerclage are at high risk for recurrent spontaneous preterm birth, and their management in the subsequent pregnancy is controversial.

The aim of this study was to evaluate management in the subsequent pregnancy for women with a prior ultrasound-indicated cerclage.

MATERIALS AND METHODS

This was a retrospective, multicenter cohort study of singleton gestations with a prior ultrasound-indicated cerclage from 1994 to 2014. Five tertiary referral centers were involved: Thomas Jefferson University Hospitals (Philadelphia, Pennsylvania), Albert Einstein Medical Center (Philadelphia, Pennsylvania), Christiana Care Health Services (Newark, Delaware), University of Naples Federico II (Naples, Italy), and the University of Bologna (Bologna, Italy). The institutional review board at each institution approved the study.

Women with a prior ultrasound-indicated cerclage who had a subsequent pregnancy were included in the analysis. We evaluated three pregnancies in the study participants. Our study participants had spontaneous preterm birth at less than 37 weeks of gestation in their first evaluated pregnancy (presenting as preterm labor or preterm premature rupture of membranes). The study participants then had an ultrasound-indicated cerclage placed in the second pregnancy for a short cervix 25 mm or less. These women were then followed in their third pregnancy, which was managed either by transvaginal ultrasound cervical length screening with ultrasound-indicated cerclage placement only if the cervical length shortened to 25 mm or less before 24 weeks of gestation or planned history-indicated cerclage. We compared the management and outcomes of women with prior ultrasound-indicated cerclage in the subsequent pregnancy (transvaginal ultrasound cervical length screening or history-indicated cerclage). We excluded women with cerclage placed for a short cervix in their first pregnancy or cerclage placed only for other risk factors of spontaneous preterm birth (such as cone biopsy, prior multiple loop electrosurgical excision procedure, dilation and curettages), and women with a prior ultrasound-indicated cerclage who had no subsequent pregnancy. We also excluded women who had an unclear indication for cerclage placement. Additionally we excluded multiple gestations, fetal anomalies, or if no data were available for indication of a prior ultrasound-indicated cerclage, or all of these.

Patients who underwent cerclage placement were identified using the existing database at Thomas Jefferson University Hospitals and a billing code system at Albert Einstein Medical Center. Cerclage patients at Christiana Care Health Services were identified from an institution data warehouse and also using surgical billing code system. The data were collected at the University of Naples and University of Bologna using surgical billing codes. We reviewed maternal medical records of at least three pregnancies in all women with a prior ultrasound-indicated cerclage. Maternal characteristics, preterm birth risk factors, cerclage indication and operative details, and perinatal outcomes data were collected for all three pregnancies in the study participants. The indication for ultrasound-indicated cerclage placement included a short cervix 25 mm or less (and rarely just for funneling greater than 25% before 2005) in women with prior spontaneous preterm birth or multiple second-trimester losses. Data from all study sites was reviewed by two authors (A.S., G.S.), and accuracy of data was verified against outpatient and hospital records (A.S. verified data from the U.S. study sites

Table 1. Maternal Demographic Characteristics in the Index Pregnancy

Characteristic	Transvaginal Ultrasound Cervical Length Screening (Experimental Group) (n=38, 37.3%)	History-Indicated Cerclage (Control Group) (n=64, 62.7%)	*P*
Age (y)	29.6±4.2	29.7±5.0	.877
Race			.838
African American	22 (57.9)	35 (54.7)	
Other	16 (42.1)	29 (45.3)	
Smoking	10 (26.3)	6 (9.5)	.046
Cone biopsy	5 (13.5)	9 (14.5)	.974
17-hydroxy progesterone caproate	22 (57.9)	35 (54.7)	.838
Before 2005	0/6 (0)	0/11 (0)	.999
During or after 2005	22/32 (68.8)	35/53 (66.0)	.721
BMI (kg/m^2)			
Mean	33.6±8.3	30.9±8.4	.174
Greater than 30	22 (57.9)	26 (40.6)	.104
Less than 19	0	3 (4.7)	.292
Gravidity	4.7±2.4	4.6±1.7	.930
No. of prior spontaneous preterm births (20 0/7–36 6/7 wk)	1.3 (1–3)	1.7 (1–3)	.035
No. of prior 2nd-trimester losses (14 0/7–19 6/7 wk)	0.6 (0–3)	0.8 (0–3)	.774
Earliest gestational age at prior spontaneous preterm birth (20 0/7–36 6/7 wk)	29.1±5.5	26.5±4.9	.087
Earliest gestational age at prior 2nd-trimester loss (14 0/7–19 6/7 wk)	16.4±1.1	17.1±1.1	.178
Prior ultrasound-indicated cerclage placement			
Gestational age (wk)	19.5±2.1	19.3±2.5	.832
Cervical length (mm)	17.6±5.8	17.5±6.6	.947
Prior ultrasound-indicated cerclage delivery			
Gestational age (wk)	34.0±7.0	31.3±7.2	.064
Delivery at less than 32 wk of gestation	11 (29.9)	30 (46.9)	.057

BMI, body mass index.
Data are mean±standard deviation, n (%), n/N (%), or median (range), unless otherwise specified.

and G.S. verified the data from Italian study sites). The deidentified data from all five institutions were combined in a single database before analysis.

At Thomas Jefferson University Hospitals, the University of Naples, and the University of Bologna, cervical cerclages were performed using the McDonald technique with one stitch of Mersilene 5-mm tape placed in a pursestring fashion. At Albert Einstein Medical Center, the McDonald technique was performed using a nonabsorbable braided polyester suture. At Christiana Care Health Services, cervical cerclage was performed using the McDonald technique using 2-Ethibond suture. At all five institutions, the indications for cerclage placement were similar. Intraoperative ultrasound guidance, antibiotics, or tocolytics were not used for the cerclage procedures. Starting at the end of 2003, 17-hydroxyprogesterone caproate weekly from 16 to 36 weeks of gestation was offered to women with prior spontaneous preterm birth at all five institutions.[14] The cerclage was removed at 36–37 weeks of gestation or earlier for preterm labor, preterm premature rupture of membranes, or if delivery was indicated at all study sites.

The primary outcome was incidence of spontaneous preterm birth at less than 37 weeks of gestation. Secondary outcomes included spontaneous preterm birth at less than 35, less than 32, less than 28, or less than 24 weeks of gestation; incidence of preterm premature rupture of membranes; birth weight; and low birth weight less than 2,500 g. Additionally, we assessed the incidence, gestational age, and outcomes of repeat ultrasound-indicated cerclage in the index pregnancy. We planned a subgroup analysis of the study participants from the United States to assess the generalizability to the U.S. population. We also compared the outcomes in two groups (transvaginal ultrasound cervical length screening, history-indicated cerclage) in women with gestational age at delivery less than 32 and 32 weeks of gestation or greater in prior pregnancy with ultrasound-indicated cerclage.

Sample size calculation was performed based on results from previous studies, which showed an overall

incidence of preterm birth at less than 37 weeks of gestation of 26% in women who underwent history-indicated cerclage[7] and 42% among women who underwent ultrasound-indicated cerclage.[4] For 80% power and a two-sided α of 0.05, 138 women in the experimental group and 138 women in the control group are required.

Statistical analysis was performed using SPSS 19.0. Data were shown as means±standard deviation or as number (%). Categorical variables were compared using the χ^2 or Fisher's exact test. Within-group comparison was undertaken using Wilcoxon and Mann-Whitney tests. $P<.05$ was considered statistically significant. Multivariate logistic regression was performed to correct data for those variables significantly different between groups. Survival curves for gestational age at delivery were obtained by Kaplan-Meier estimated and compared by Cox regression. The study was performed following the Strengthening The Reporting of OBservational studies in Epidemiology guidelines.[15]

RESULTS

We reviewed a total of 1,709 charts at the study sites. Of these 1,709, we identified 157 women who had a subsequent pregnancy after a prior ultrasound-indicated cerclage. After review of medical records, 55 women were excluded and remaining the 102 singleton gestations with a prior ultrasound-indicated cerclage were included in the study (Fig. 1). Of these 102 women with prior ultrasound-indicated cerclage, in the next pregnancy, 38 (37.3%) had transvaginal ultrasound cervical length screening, whereas 64 (62.7%) women underwent planned history-indicated cerclage. Of the 38 women who were managed with transvaginal ultrasound cervical length screening, 18 (47.4%) women underwent ultrasound-indicated cerclage for cervical length 25 mm or less.

Demographic characteristics were similar in the transvaginal ultrasound cervical length screening and history-indicated cerclage groups, except for a significantly higher rate of smoking in the transvaginal ultrasound cervical length screening group ($P=.04$) and higher number of prior spontaneous preterm birth in the history-indicated cerclage group ($P=.03$) (Table 1).

After adjusting for confounders (smoking, number and earliest gestational age of prior spontaneous preterm birth[s], and gestational age at delivery in prior pregnancies), the primary outcome, the rate of spontaneous preterm birth at less than 37 weeks of gestation, was similar between transvaginal ultrasound cervical length screening and history-indicated cerclage (36.8% compared with 43.8%; adjusted odds ratio 0.77, 95% confidence interval 0.47–1.45; Table 2). A similar pattern was noted for each of the secondary outcomes (Table 2). Approximately 39% of women with ultrasound-indicated cerclage in the index pregnancy

Table 2. Primary and Secondary Outcomes in the Index Pregnancy

Outcome	Transvaginal Ultrasound Cervical Length Screening (Experimental Group) (n=38, 37.3%)	History-Indicated Cerclage (Control Group) (n=64, 62.7%)	OR (95% CI)	Adjusted OR (95% CI)
Gestational age at delivery (wk)	35.7±5.5	34.2±6.9	Mean difference −1.5 wk (95% CI −3.96 to 0.96)	NA
Spontaneous preterm birth (wk of gestation)				
Less than 37	14 (36.8)	28 (43.8)	0.87 (0.21–2.58)	0.77 (0.47–1.45)
Less than 35	6 (15.8)	18 (28.1)	0.74 (0.27–2.63)	0.71 (0.33–2.45)
Less than 32	6 (15.8)	14 (21.9)	0.84 (0.49–2.59)	0.84 (0.52–2.33)
Less than 28	5 (13.2)	13 (20.3)	0.77 (0.17–33.64)	0.63 (0.13–7.87)
Less than 24	3 (7.9)	8 (12.5)	1.86 (0.02–3.72)	1.11 (0.42–6.54)
Preterm PROM	6 (15.8)	8 (12.5)	1.11 (0.94–3.12)	1.07 (0.88–3.02)
Birth weight (g)	2,789±852	2,693±1,019	Mean difference −96.00 g (95% CI −464.39 to 272.39)	NA
Low birth weight*	8 (21.1)	15 (23.4)	0.94 (0.73–1.17)	0.81 (0.31–2.03)

OR, odds ratio; CI, confidence interval; NA, not applicable; PROM, premature rupture of membranes.
Data are mean±standard deviation or n (%)unless otherwise specified.
* Birth weight less than 2,500 g.

delivered before 37 weeks of gestation and had a lower mean gestational age at delivery (33.8±6.9 weeks of gestation). Kaplan-Meier survival curve for gestational age at delivery showed no statistically significant benefit in transvaginal ultrasound cervical length screening compared with history-indicated cerclage management (P=.26) (Fig. 2).

Additionally, we performed a subgroup analysis of primary and secondary outcomes in women who delivered at less than 32 weeks and 32 weeks of gestation or greater with their prior ultrasound-indicated cerclage pregnancy in the two study groups (transvaginal ultrasound cervical length screening, history-indicated cerclage). The outcomes were noted to be similar in two study groups in women with a prior ultrasound-indicated cerclage who delivered at less than 32 weeks of gestation in their prior pregnancy and in women who delivered at 32 weeks of gestation or greater in a prior pregnancy with ultrasound-indicated cerclage. Overall we noted a higher rate of spontaneous preterm birth at less than 37 weeks of gestation and lower gestational age at delivery in women who delivered at less than 32 weeks of gestation compared with those who delivered at 32 weeks of gestation or greater in a prior pregnancy with ultrasound-indicated cerclage (Table 3). All women (n=7) who delivered at less than 32 weeks of gestation in their prior pregnancy and subsequently had transvaginal ultrasound screening received ultrasound-indicated cerclage in the index pregnancy, compared with only 35.5% of women who delivered at 32 weeks of gestation or greater in their prior pregnancy (Table 3).

We also performed a subanalysis of study participants from the U.S. study sites (Thomas Jefferson University Hospitals, Albert Einstein Medical Center, Christiana Care Health Services). Results were similar to the overall analysis (Appendices 1–3, available online at http://links.lww.com/AOG/A701).

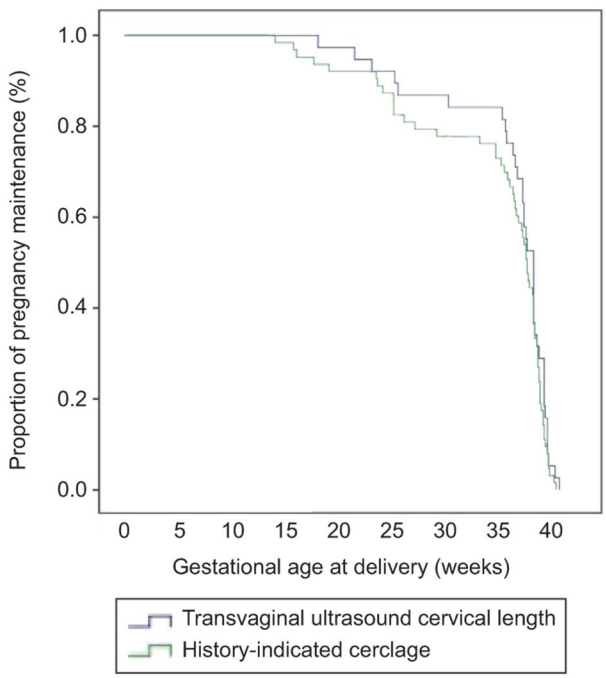

Fig. 2. Kaplan-Meier curves for pregnancy maintenance in women who were followed with transvaginal ultrasound cervical length screening and those who underwent history-indicated cerclage. P=.26 (Cox regression).

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DISCUSSION

This multicenter retrospective study showed that women with prior ultrasound-indicated cerclage have similar outcomes if they receive in the subsequent pregnancy either transvaginal ultrasound cervical length screening with ultrasound-indicated cerclage for cervical length 25 mm or less or a planned history-indicated cerclage. Less than 50% of the women in the transvaginal ultrasound cervical length screening group required a repeat ultrasound-indicated cerclage in the subsequent pregnancy. The outcomes were noted overall to be similar in two subgroups of women with prior ultrasound-indicated cerclage who delivered either at less than 32 weeks or 32 weeks of gestation or greater in the prior pregnancy with ultrasound-indicated cerclage.

The old myth of "once a cerclage, always a cerclage in subsequent pregnancy" has been proven wrong by available evidence.[3,16–18] Fejgin et al[18] in 1994 suggested that in patients with a history of prior cerclage for nontraditional indications, a repeat history-indicated cerclage may not be indicated and may in fact be deleterious to the woman and the pregnancy. Pelham et al[16] also noted that the outcomes and rate of preterm birth in women with a prior cerclage (history-indicated cerclage or ultrasound-indicated cerclage) for untraditional (unclear or inappropriate) indications other than cervical insufficiency are noted to be similar in transvaginal ultrasound screening and history-indicated cerclage in the subsequent pregnancy. Limited literature of prior cerclage (combined history-indicated cerclage and ultrasound-indicated cerclage) showed no benefit of repeat cerclage in subsequent pregnancy.[16] Our study results suggest that women with a prior ultrasound-indicated cerclage could be safely managed with transvaginal ultrasound cervical length screening and help

Table 3. Subgroup Analysis of Outcomes of Women With Prior Preterm Birth at Less Than 32 Weeks of Gestation or 32 Weeks of Gestation or Greater in Women With Prior Ultrasound-Indicated Cerclage

	Spontaneous Preterm Birth at Less Than 32 Wk of Gestation in the Pregnancy With Prior Ultrasound-Indicated Cerclage (n=34, 33.3%)			Spontaneous Preterm Birth at 32 Wk of Gestation or Greater in the Pregnancy With Prior Ultrasound-Indicated Cerclage (n=68, 66.7%)		
Outcome	Transvaginal Ultrasound Cervical Length Screening (Experimental Group) (n=7, 20.6%)	History-Indicated Cerclage (Control Group) (n=27, 79.4%)	Adjusted OR (95% CI)	Transvaginal Ultrasound Cervical Length Screening (Experimental Group) (n=31, 45.6%)	History-Indicated Cerclage (Control Group) (n=37, 54.4%)	Adjusted OR (95% CI)
Gestational age at delivery (wk)	29.9±8.7	30.4±8.2	*P*=.888	36.9±3.7	36.8±4.4	*P*=.873
Spontaneous preterm birth (wk of gestation)						
Less than 37	4 (57.1)	16 (59.3)	0.97 (0.47–1.97)	8 (25.8)	11 (29.7)	0.87 (0.40–1.89)
Less than 35	4 (57.1)	14 (51.9)	1.10 (0.53–2.30)	2 (6.5)	3 (8.1)	0.80 (0.14–4.46)
Less than 32	4 (57.1)	12 (44.4)	1.29 (0.60–2.77)	2 (6.5)	2 (5.4)	1.19 (0.18–7.99)
Less than 28	3 (42.9)	11 (40.7)	1.40 (0.64–3.08)	2 (6.5)	2 (5.4)	1.19 (0.18–7.99)
Less than 24	2 (28.6)	6 (22.2)	1.29 (0.33–5.05)	1 (3.2)	1 (2.7)	1.19 (0.08–18.31)
Preterm PROM	3 (42.9)	7 (25.9)	1.65 (0.57–4.80)	3 (9.7)	1 (2.7)	3.58 (0.39–32.71)
Birth weight (g)	1,957±1,364	2,172±1,285	*P*=.738	2,956±619	3,035±607	*P*=.607
Low birth weight*	3 (42.9)	9 (33.3)	1.57 (0.54–2.74)	1 (3.2)	1 (2.7)	1.19 (0.08–18.31)
Incidence of ultrasound-indicated cerclage	7 (100)	NA	NA	11 (35.5)	NA	NA

OR, odds ratio; CI, confidence interval; PROM, premature rupture of membranes; NA, not applicable.
Data are mean±standard deviation or n (%)unless otherwise specified.
* Birth weight less than 2,500 g.

avoid cerclage in approximately 50% of women, in whom cervical length remains greater than 25 mm in the subsequent pregnancy. Our study data support the previously published meta-analysis that only 42% women developed a short cervix and received ultrasound-indicated cerclage in transvaginal ultrasound cervical length screening in women with prior preterm birth with a short cervix.[5] Moreover, our results concur with a very recent European study.[19] In this small cohort study, also including women who underwent planned abdominal cerclage, women with a prior ultrasound-indicated cerclage who received history-indicated cerclage had a similar outcome compared with those who underwent cervical surveillance in the next pregnancy.[19]

One of the strengths of our study is the inclusion of a specific population, that is, singleton gestations with a prior ultrasound-indicated cerclage. This is the first study evaluating this clinical dilemma specifically between planned history-indicated cerclage compared with transvaginal ultrasound cervical length screening with ultrasound-indicated cerclage as indicated. No similar publications were found by a systematic review: searches were performed in MEDLINE, Scopus, Sciencedirect.com, ClinicalTrials.gov, and EMBASE with the use of the following keywords: "cerclage," "cervical cerclage," "ultrasound indicated cerclage," "history indicated cerclage," and "preterm birth from beginning of each database to May 2015" Primary and secondary outcomes were established as a priori. As a result of the multicenter and multinational nature of our study, we performed a subanalysis of women from the U.S. sites only, and the outcomes in study subjects from the United States were noted to be similar comparing all study participants. Our study data support that ultrasound-indicated cerclage is beneficial for a subset of women who undergo transvaginal ultrasound cervical length screening, and history-indicated cerclage should not be offered as the one and only option to these women.

There are two important limitations of our study. First, it is a retrospective, nonrandomized comparison of patients accrued over 20 years at five centers. Therefore, the potential for treatment as well as ascertainment bias is great. Second, our study is markedly underpowered, because we accrued less than half of our necessary sample size. This lack of power is only intensified in the subgroup analyses. An additional limitation is that we were unable to obtain neonatal data including prematurity complications such as respiratory distress syndrome, intraventricular hemorrhage, necrotizing enterocolitis, neonatal sepsis, and neonatal death.

In summary, in this retrospective study, women with prior ultrasound-indicated cerclage had similar outcomes whether they received either transvaginal ultrasound cervical length screening with ultrasound-indicated cerclage for cervical length 25 mm or less or planned history-indicated cerclage in the subsequent pregnancy.

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